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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/719,236      | 04/19/2001  | David Geraint Owen   | 07203.0024          | 6215             |

7590 05/14/2004  
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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/719,236             | OWEN ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MY-CHAU T TRAN         | 1639                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-56 is/are allowed.
- 6) ☒ Claim(s) 1-19 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/31/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

***Status of Claims***

2. Applicant's amendment filed 3/29/04 is acknowledged and entered. Claims 23-28 have been canceled.
3. Claims 20-21, 29-38, and 46 are canceled by the amendment filed on 10/21/02.
4. Claims 39-45 are canceled by the preliminary amendment filed on 7/18/02.
5. Claims 1-19, 22, and 47-56 are pending.
6. This application is a 371 of PCT/GB99/01871 filed 6/14/99, which claims priority under 35 U.S.C. 119(a)-(d) to a foreign application 9812783.0 filed 6/12/98.
7. Claims 1-19, and 47-56 are treated on the merit in this Office Action.

***Withdrawn Objections and /or Rejections***

8. In view of applicant's arguments, the previous rejection under 35 USC 112, first paragraph (new matter) has been withdrawn.

Art Unit: 1639

9. In view of applicant's arguments, the rejection of claims 1, 13, and 15-17 under 35 USC 103(a) as being obvious over Osman et al. (US Patent 5,234,566) in view of Fare et al. (US Patent 5,225,374) has been withdrawn.

10. In view of applicant's cancellation of claims 23-28, the rejection of claims 23-28 under 35 USC 103(a) as being obvious over Olesen et al. (US Patent 6,063,260) and Kovacs et al. (US Patent 5,981,268) has been withdrawn.

11. In view of applicant's arguments, the rejection of claims 47-56 under 35 USC 103(a) as being obvious over Kovacs et al. (US Patent 5,981,268) and Fare et al. (US Patent 5,225,374) has been withdrawn.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomich et al. (US Patent 5,368,712).

Tomich et al. disclose a biosensor for detecting the presence or changes in an electrical potential of an ion channel protein (col. 19, lines 34-41). The biosensor comprises a synthetic cell membrane (biological membrane) with ion channel protein pore; the membrane separates two compartments (a solution perfusion channel); and a shield is placed across the membrane (adhered to a substrate) (col. 19, lines 15-33, and 54-65). The shield comprises a porous screen (porous substrate). Thus the biosensor of Tomich et al. anticipates the presently claimed device.

14. Claims 1, 4, 6, 8, 9, 13, 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ma et al. (*Biochem. And Biophys. Res. Comm.*, 1997, 232(2):461-463).

Ma et al. disclose a device for measuring transmembrane ion-transmission properties such as  $\text{Ca}^{2+}$  under a voltage-clamp mode (Abstract). The device comprises a planar lipid bilayer membrane (biological membrane) with ion channel that is attached to a Teflon partition (porous substrate) (pg. 461, right col., line 33 to pg. 462, line 5). The partition separates two compartments (a solution perfusion channel). The device is connected to a patch-clamp amplifier. Thus the device of Ma et al. anticipates the presently claimed device.

15. Claims 1, 4, 6, 8, 9, 13, 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al. (*Biochim. Et Biophys. Acta*, 1997, 1323(1):117-129).

Chan et al. disclose a device for measuring ionic fluxes in ion channels such as  $\text{K}^{+}$  and  $\text{Na}^{+}$  under a voltage-clamp mode (Abstract). The device comprises a planar lipid bilayer membrane (biological membrane) with ion channel that is attached to a Teflon membrane (porous substrate) (pg. 118, right col., line 34 to pg. 119, line 22). The Teflon membrane

Art Unit: 1639

separates two compartments (a solution perfusion channel). The device is connected to a patch-clamp system. Thus the device of Chan et al. anticipates the presently claimed device.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. (*Biochim. Et Biophys. Acta*, **1997**, 1323(1):117-129) and Olesen et al. (US Patent 6,063,260: *filing date 4/25/1997*).

Chan et al. disclose a device for measuring ionic fluxes in ion channels such as K<sup>+</sup> and Na<sup>+</sup> under a voltage-clamp mode (Abstract). The device comprises a planar lipid bilayer membrane (biological membrane) with ion channel that is attached to a Teflon membrane

Art Unit: 1639

(porous substrate) (pg. 118, right col., line 34 to pg. 119, line 22). The Teflon membrane separates two compartments (a solution perfusion channel). The device is connected to a patch-clamp system.

The device of Chan et al. does not expressly include biological membrane such as cell and substrate such as glass.

Olsen et al. disclose a high throughput patch clamp apparatus (Abstract). The patch clamp comprise of a membrane ion channel of a cultured cell, which is position on a coverslip (col. 9, lines 57-67). The patch electrode pipette comes into contact with the membrane and a giga-seal is created between the pipette and the membrane by way of suction. An electrical signal is detected by an electrode in the patch pipette (col. 10, lines 1-2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include biological membrane such as cell and substrate such as glass as taught by Olesen et al. in the apparatus of Chan et al. One of ordinary skill in the art would have been motivated to include biological membrane such as cell and substrate such as glass in the apparatus of Chan et al. because the type of biological membrane and substrate use would be a choice of experimental design and is considered within the purview of the cited prior art since both Chan et al. and Olesen et al. disclose monitor voltage impedance from cell membrane using a patch clamp apparatus (Olesen: col. 1, lines 8-21; Chan: pg. 119, lines 11-12). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Chan et al. and Olesen et al. because Olesen et al. disclose of measuring  $\text{Ca}^{2+}$  currents of a chick dorsal root ganglion cell using the patch clamp device (col. 15, lines 11-58).

***Allowable Subject Matter***

19. Claims 47-56 are allowed. The following is a statement of reasons for the indication of allowable subject matter:

The combination of the structural limitations for the presently claimed apparatus (i.e. a high throughput screen) wherein a porous substrate disposed in the well and spaced from the bottom to define a solution perfusion channel between the well bottom and substrate, a first electrode in the well in electrical communication with a bottom side of the substrate, and a second electrode disposed in the well in electrical communication with a topside of the substrate is not taught or suggested by the cited prior arts.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct  
May 12, 2004



PADMASHRI PONNALURI  
PRIMARY EXAMINER